UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MEDLINE INDUSTRIES, LP, Plaintiff, v. C.R. BARD, INC., Defendant.	Case No. 16-cv-03529 Judge Martha M. Pacold

MEMORANDUM OPINION AND ORDER

Medline Industries alleges that C.R. Bard directly infringes claims 1–8, 10, and 11 of U.S. Patent No. 9,283,352 ("the '352 patent") and claims 1, 10–12, 14, 16, 19, 22, and 28 of U.S. Patent No. 9,522,753 ("the '753 patent") through Bard's manufacture and sale of the SureStep Foley Catheterization Kit (the "SureStep Kit"). [312-2] ¶ 2.[1] The '352 patent claims a catheterization procedure system, and the '753 patent claims a method of packaging a medical procedure kit.[2]

There are four summary judgment motions currently before the court: Medline's motion for partial summary judgment of infringement of the '352 and '753 patents, [312]; Bard's motion for summary judgment of non-infringement of the '352 and '753 patents, [315]; Bard's motion for summary judgment of non-infringement of the '753 patent under 35 U.S.C. § 271(a), [314]; and Medline's motion for summary judgment on Bard's Fifth Additional Defense, [310].

On April 12, 2023, Bard informed the court that the Patent and Trademark Office had issued a final rejection in its reexamination of the '753 patent. [467]. The parties do not dispute that the court should defer ruling on aspects of the pending motions pertaining specifically to that patent until the conclusion of the reexamination proceedings. *See* [471].

[1] Bracketed numbers refer to docket entries and are followed by the page or paragraph number. Page numbers refer to the CM/ECF page number.

[2] Medline originally alleged infringement of U.S. Patent No. 8,746,452 ("the '452 Patent") but no longer asserts infringement of the '452 Patent. [312-2] ¶ 2.

For the reasons that follow, Medline's motion for partial summary judgment of infringement, [312], is granted in part and denied in part. The motion is granted in the following respects: (1) summary judgment is granted for Medline and against Bard with respect to infringement of claims 1–6, 8, and 10 of the '352 patent; (2) under Rule 56(g), summary judgment is granted for Medline and against Bard in that Bard is precluded from advancing its "use" argument as to claim 7 of the '352 patent. Bard's motion for summary judgment of non-infringement, [315], is denied with respect to the '352 patent. Medline's motion for summary judgment on Bard's Fifth Additional Defense, [310], is granted. All motions are denied without prejudice to the extent they request relief with respect to the '753 patent. That is, the court denies, without prejudice to refiling at the conclusion of the reexamination proceedings, (1) any relief requested with respect to the '753 patent in the motions already listed ([310], [312], [315]), as well as (2) Bard's motion for summary judgment of non-infringement of the '753 patent under 35 U.S.C. § 271(a), [314].

BACKGROUND

The patents and allegedly infringing products concern urinary catheterization kits and their packaging. A urinary catheter is a thin tube placed in the bladder to drain urine, which then drains through a tube into a collection bag. The catheterization process is the process of inserting the catheter into a patient's bladder. Maintaining the sterility of the catheter, including throughout its insertion, is an important goal in order to avoid introducing germs that could harm patients. *See* [105] ¶ 15.

Medline and Bard have been involved in extensive patent litigation over catheterization kits. This is the second of three actions that Medline has filed against Bard in this district. *See* Case Nos. 14-cv-03618 (N.D. Ill.) ("*Medline I*") and 17-cv-07216 (N.D. Ill.) ("*Medline III*").

As to the patents at issue in this case: Medline's '352 patent is for a "catheterization procedure system," which includes the necessary components for a catheterization (e.g., the catheter, fluid bag, lubricating jelly, syringes) laid out in a single-level tray. [321-1] at 2–4 ¶¶ 5, 6. Medline's '753 patent is for a method of packaging such a medical procedure kit. *Id.* at 4–5 ¶ 7. (Again, the court does not reach the parties' requests for relief with respect to the '753 patent, pending the reexamination.)

One significant dispute at this juncture is in the details of the layout of components in catheterization kits. In particular, Medline's '352 patent protects a kit where two syringes are "ordered . . . in accordance with their use during the catheterization procedure."

Bard manufactures "SureStep" catheterization kits. Bard sells two versions of its SureStep Kit: one kit with a smaller tray with a drainage bag ("SureStep Bag Tray" or "SureStep Bag Kit") and the other kit with a larger tray with a urine meter ("SureStep Meter Tray" or "SureStep Meter Kit"). [321-1] at 6 ¶ 10. Bard began selling its SureStep Kit in March of 2014. *Id.* at 6 ¶ 9.

Each version of the SureStep Kit comes with two syringes—a water syringe and a lubrication syringe. *Id.* at 9 ¶ 24. In the SureStep Bag Tray, the water syringe (with clear plunger in the photos below) is placed partially on top of and to the left of the lubrication syringe (with green plunger in the photos below); in the SureStep Meter Tray, the water syringe is placed to the left of the lubrication syringe:

Current Version of SureStep Bag Tray

Current Version of SureStep Meter Tray

Id.

The SureStep Kit is used in a Foley catheterization procedure. *See id.* at 27 ¶ 55. Generally, during a Foley catheterization procedure, the catheter is lubricated; the insertion site is cleaned; the catheter is inserted; and water is injected into the catheter, inflating a small balloon at the other end of the catheter so that the catheter remains in place.

Medline accuses Bard of infringing certain claims of Medline's '352 patent by manufacturing and importing the SureStep Kit. Again, the dispute comes down to a claim limitation in the '352 patent requiring that two syringes be "ordered . . . in accordance with their use during the catheterization procedure" (the "order of use" limitation). Claim 1 of the '352 patent recites:

> A catheterization procedure system to accommodate a catheter, a fluid bag, and one or more medical devices, comprising:
>
> a single level tray comprising a contoured surface defining at least two compartments separated by a wall, the at least
>
> two compartments comprising a first compartment and a second compartment;
>
> a first syringe and a second syringe; and

the catheter and the fluid bag, the catheter attached to the fluid bag;

wherein:

> the first syringe and the second syringe are disposed within the first compartment;
>
> one of the first syringe or the second syringe is for use in a catheterization procedure before another of the first syringe or the second syringe and the first syringe and the second syringe are *ordered* within the first compartment *in accordance with their use during the catheterization procedure*;
>
> the catheter and the fluid bag are disposed within the second compartment; and
>
> the first compartment defines a lubricating jelly application compartment to receive lubricating jelly from the one of the first syringe or the second syringe to lubricate the catheter when the catheter is passed from the second compartment into the first compartment;
>
> the first compartment is further bounded by a first compartment base member and at least a first portion of a perimeter wall;
>
> the second compartment is further bounded by a second compartment base member and at least a second portion of the perimeter wall;
>
> the perimeter wall terminates at a horizontal flange; and
>
> the perimeter wall extends from at least a portion of the first compartment base member to the horizontal flange by a height that is greater than or equal to half of another height that the perimeter wall extends from the second compartment base member to the horizontal flange.

[321-1] at 2–3 ¶ 5 (emphasis added). Claims 2–8 and 10 of the '352 patent depend from claim 1, so they incorporate the order of use limitation. *Id*. at 3–4 ¶ 6. Claim 7 of the '352 patent recites: "The catheterization procedure system of claim 1, the contoured surface defining a mnemonic device indicating which of the first syringe or the second syringe should be *used first in the catheterization procedure*." *Id.* (emphasis added).

Medline served final infringement contentions for the '352 patent on August 26, 2016, and supplemental final infringement contentions on September 1, 2017 (a scheduling order reset Medline's deadlines after Medline added the '753 patent to this action; as a result, Medline served the supplemental final infringement contentions on September 1, 2017). [321-1] at 6 ¶ 11. Medline served supplemental final infringement contentions for the '753 patent on May 29, 2017. *Id.* at 7 ¶ 14. Bard served final non-infringement contentions for both patents on September 29, 2017. *Id.* at 7 ¶ 15.

The court held a *Markman* hearing on March 26 and 27, 2018, *see* [146], [147], and issued a *Markman* ruling on December 28, 2018, *see* [171]. Among other things, the court construed "mnemonic device" as "feature intended to assist the memory. [171].

This case was reassigned to the current judge, [239], and the parties completed fact and expert discovery, [283]. Currently at issue are the four summary judgment motions. [310]; [312]; [314]; [315].

LEGAL STANDARD

Summary judgment is proper where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The substantive law controls which facts are material. *Id.*

The party seeking summary judgment has the burden of establishing that there is no genuine dispute as to any material fact. *See Celotex*, 477 U.S. at 323. After a "properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250 (cleaned up). Construing the evidence and facts supported by the record in favor of the nonmoving party, the court gives the nonmoving party "the benefit of reasonable inferences from the evidence, but not speculative inferences in [the party's] favor." *White v. City of Chicago*, 829 F.3d 837, 841 (7th Cir. 2016) (citations omitted). "The controlling question is whether a reasonable trier of fact could find in favor of the non-moving party on the evidence submitted in support of and opposition to the motion for summary judgment." *Id.* (citation omitted).

A court treats cross-motions for summary judgment separately and construes all facts and draws all reasonable inferences in favor of the party against whom the

motion was filed. *Indianapolis Airport Auth. v. Travelers Prop. Cas. Co. of Am.*, 849 F.3d 355, 361 (7th Cir. 2017); *see also Kreg Therapeutics, Inc. v. VitalGo, Inc.*, 919 F.3d 405, 416 (7th Cir. 2019) ("Each cross movant for summary judgment bears a respective burden to show no issue of material fact with respect to the claim.").

ANALYSIS

I. Medline's Motion For Partial Summary Judgment Of Infringement [312] And Bard's Motion For Summary Judgment Of Non-Infringement Of The '352 Patent [315]

Medline's motion for partial summary judgment of infringement asks that the court: (1) enter partial summary judgment that the SureStep Kit meets the "ordered . . . in accordance with their use during the catheterization procedure" limitation in claims 1–8 and 10 of the '352 patent and claim 12 of the '753 patent; (2) enter summary judgment that the SureStep Kit infringes claims 1–6, 8, and 10 of the '352 patent; and (3) preclude Bard from advancing its "use" argument as to the "mnemonic device" limitation for claim 7 of the '352 patent and claim 1 of the '753 patent. [312]. Bard cross moves for summary judgment of non-infringement of claims 1–8 and 10 of the '352 patent and all asserted claims of the '753 patent. [315]. As discussed in the introduction, this opinion makes no conclusions with respect to the '753 patent because of the pending reexamination proceedings. As to the '352 patent, Medline's motion [312] is granted, and Bard's motion [315] is denied.

Both parties' summary judgment motions turn on whether the SureStep Kit (and in particular, the syringes within the SureStep Kit) meets the "ordered . . . in accordance with their use during the catheterization procedure" limitation (the order of use limitation). The summary judgment motions primarily concern the term "use" and the order in which the syringes in the SureStep Kit are "used." The court has not engaged in prior claim construction of the term "use."

The parties do not dispute that the syringes in the SureStep Kit are ordered left-to-right, with the water syringe (with clear plunger) on the left and the lubrication syringe (with green plunger) on the right. That is, in the SureStep Kit, the water syringe is ordered before the lubrication syringe.

The question is whether the order in which the syringes are arranged in the kit—with the water syringe before the lubrication syringe—corresponds with the order of their use during catheterization. In other words, the question is whether the water syringe is used before or after the lubrication syringe during catheterization.

Bard contends that the order in which the syringes are arranged in the SureStep Kit does not correspond with the order in which they are used during catheterization. Bard begins by arguing that in the context of a syringe, the ordinary meaning of "use" is "injecting stored contents." [315] at 8–10. Put another way, under Bard's construction, a syringe is not "used" until its contents are injected. Bard then argues that during a catheterization, the catheter must be lubricated before insertion (requiring injection of lubricant from the lubricant syringe), and then only after the catheter is inserted is the catheter balloon inflated with water (requiring injection of water from the water syringe) such that the catheter remains in place. According to Bard, the SureStep Kit's Directions for Use specifically instruct practitioners to use the lubrication syringe first (by injecting the lubrication syringe's contents into the tray, in order to lubricate the catheter) *before* using the water syringe (to inject the water into the catheter). Bard argues that this sequence directly contradicts Medline's patent, which according to Bard directs practitioners to use the water syringe first (to inflate a test balloon with water) *before* using the lubrication syringe (by injecting the lubrication syringe's contents into the tray, in order to lubricate the catheter. Thus, Bard contends, in the SureStep Kit, the lubricant syringe is used *before* the water syringe. [315] at 15–16; [321] at 10–11. Bard argues that the syringes in the SureStep Kit are not arranged in their order of use, so the SureStep Kit does not infringe any claim of the '352 patent. [315] at 15–16.

Medline counters that Bard did not advance its non-infringement "order of use" theory until expert discovery, and so Bard has waived reliance on its proposed definition of "use" and its argument that the syringes are not ordered in accordance with their use. [312-1] at 4–7; *see* [312-5] at 5. Alternatively, Medline also advances its own construction of the term "use"—that "use" means "accessed and manipulated by a clinician performing a catheterization procedure"—and moves for summary judgment of infringement based on its construction.

A. Bard's Waiver Of Its Order Of "Use" Non-Infringement Theory

Local Patent Rule 2.3(a) provides:

> Non-Infringement Contentions shall contain a chart . . . that separately indicates, for each identified element in each asserted claim, to the extent then known by the party opposing infringement, whether such element is present literally or under the doctrine of equivalents in each Accused Instrumentality and, if not, each reason for such denial and the relevant distinctions. Conclusory denials are not permitted.

"The purpose of . . . the local patent rules in general, is to require parties to crystallize their theories of the case early in the litigation so as to prevent the shifting sands approach to claim construction." *Keranos, LLC v. Silicon Storage*

Tech., Inc., 797 F.3d 1025, 1035 (Fed. Cir. 2015) (internal quotation marks omitted); *see also O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1364 (Fed. Cir. 2006) (the "local rules in question are not only unique to patent cases but also are likely to directly affect the substantive patent law theories that may be presented at trial"). Patent litigants in the Northern District of Illinois are required to comply with the Local Patent Rules. *See* LPR 1.1. "The Court has broad discretion to manage discovery matters and enforce the Local Patent Rules." *Oil-Dri Corp. of Am. v. Nestle Purina PetCare Co.*, No. 15-cv-1067, 2018 WL 3130943, at *4 (N.D. Ill. June 26, 2018).

Another court in this district addressed a similar issue in *Medline I*. In *Medline I*, Medline alleged that Bard infringed claim 1 of Patent No. 8,448,786 ("the '786 patent"), directed at a method of packaging a catheter tray kit. Order at 2, *Medline Indus., Inc. v. C.R. Bard, Inc.*, No. 14-cv-3618 (N.D. Ill. Mar. 30, 2022), ECF No. 694. Bard contended that there was no infringement of the '786 patent because the SureStep Kit omits one of claim 1's method steps. *Id.* at 5. But Bard had not disclosed this non-infringement theory in its final non-infringement contentions and only did so during expert discovery. *Id.* at 6–8. Bard was precluded from relying on this non-infringement theory to avoid summary judgment, and summary judgment was granted in Medline's favor on direct infringement. *Id.* at 8, 12.

Similarly, here, Bard did not disclose the non-infringement theory it is now presenting—that the syringes are not placed in the order of their "use" because "use" has a particular meaning, and because the SureStep Kit does not instruct a practitioner to use the water syringe first by inflating a test balloon—during the parties' exchange of final infringement and non-infringement contentions. For claim 1 of the '352 patent, Bard's final non-infringement contentions, exchanged on September 29, 2017, stated, as relevant:

U.S. Patent No. 9,283,352	
Claim	**Bardex I (SureStep)**
1. A catheterization procedure system to accommodate a catheter, a fluid bag, and one or more medical devices, comprising:	
(e) one of the first syringe or the second syringe is for use in a catheterization procedure before another of the first syringe or the second syringe and the first syringe and the second syringe are ordered within the first compartment in accordance with their use during the catheterization procedure;	Not present literally or under the doctrine of equivalents ("DOE"). At least "one of the first syringe or the second syringe is for use in a catheterization procedure before another of the first syringe or the second syringe and the first syringe and the second syringe are ordered within

	the first compartment in accordance with their use during the catheterization procedure" is missing with respect to the meter tray. The syringes of the meter tray are presented end-to-end at the same height within the tray. Thus, they are not "ordered within the first compartment in accordance with their use during the catheterization procedure."

[312-15] at 2–3. The "end-to-end" argument differs from the argument that Bard makes now as to the meaning of "use."

As to Bard's final non-infringement contentions for the '753 patent, it is unclear that non-infringement contentions concerning one patent ('753) ever could have provided Medline notice of arguments Bard might raise with respect to a different patent ('352); but in any event, the '753 final non-infringement contentions did not raise the "use" argument either. Bard's '753 final non-infringement contentions stated, in relevant part:

U.S. Patent No. 9,522,753	
Claim	**Bardex I (SureStep)**
1. A method of packaging a medical procedure kit comprising:	
1(b) placing the coiled medical device, the first syringe, and the second syringe within the single level tray, the placing comprising placing the first syringe in a first compartment defining a mnemonic device indicating which of the first syringe or the second syringe should be used first in a catheterization procedure;	Not present literally or under the doctrine of equivalents ("DOE"). Also, the limitation "the placing comprising placing the first syringe in a first compartment defining a mnemonic device indicating which of the first syringe or the second syringe should be used first in a catheterization procedure" is indefinite. To the extent the meaning of this claim limitation is understandable, at least "the placing comprising placing the first syringe in a first compartment defining a mnemonic device indicating which of the first syringe or the second syringe

	should be used first in a catheterization procedure" is missing. Plaintiff points to instructions printed on the tray as satisfying the limitation. But these instructions are not a "mnemonic device." Notably, they are not ordered left-to-right. Nor can instructions printed on a tray constitute a "a first compartment defining a mnemonic device," as the Patent Examiner expressly recognized during the prosecution of the '753 Patent. To the extent, Medline is pointing to the flat surface of the tray or the walls of the tray, they also would not constitute a mnemonic device.

[312-16] at 2–3 (footnote omitted). These arguments concerned the meaning of "mnemonic device," a term that was construed in the prior claim construction ruling and that is not at issue in the current summary judgment motions. Thus, in neither of Bard's final non-infringement contentions did Bard advance the theory that the '352 patent was not infringed because of a specific definition of "use" of a syringe or because the SureStep Kit does not instruct a practitioner to use the water syringe first (by inflating a test balloon).

The parties sent each other interrogatories regarding their order of use arguments. On January 29, 2019, Bard served its Interrogatory No. 16, asking Medline to provide details about its position regarding the "mnemonic device" limitation, including "which syringe in the Bard tray Medline contends is used first in a catheterization procedure." [321-1] at 36–37 ¶ 7; [332-1] at 8–9 ¶ 7. Medline responded to this interrogatory on February 28, 2019, describing its infringement theory as to the mnemonic device and order of use claim limitations with annotated pictures of the SureStep Kit. [332-1] at 1–10 ¶¶ 1–9.

On April 10, 2019, Medline served its Interrogatory No. 16, asking Bard about which syringe Bard contended was "used" first in the SureStep Kit, specifically:

> Describe with specificity any feature or features of the tray of the accused products that indicate when each syringe should be used in a catheterization procedure. Your answer should address separately the SureStep bag tray and the SureStep urine meter tray and include at least the following: which syringe in the tray Bard contends *is used first*

> in a catheterization procedure; which syringe in the tray Bard contends *is used second* in a catheterization procedure; what feature or features of the tray Bard contends indicate which of the first syringe or second syringe *should be used first* in a catheterization procedure; how such a feature assists the user with respect to determining which of the first syringe or the second syringe *should be used first* in a catheterization procedure; and all evidence that Bard intends to rely upon to show how Bard intended each such feature to assist the user in determining when to use each syringe.

[321-6] at 5 (emphases added).

Bard responded to this interrogatory on May 10, 2019. In its response, Bard revealed its order of use arguments that (1) the SureStep Kit did not infringe the patents because the lubricant syringe was used before the water syringe and (2) in contrast with Medline's patent, Bard did not instruct practitioners to inflate a test balloon with water first. Bard's May 10, 2019 response stated as relevant:

> Bard states that there are no features of the tray of the accused products, including both the SureStep bag tray and the SureStep urine meter tray, that indicate when each syringe should be used in a catheterization procedure. The SureStep trays are Foley catheter kits which include a lubricant-filled syringe and a water-filled syringe. The lubricant-filled syringe is used to lubricate the Foley catheter prior to insertion. The water-filled syringe is used to inflate the balloon [*sic*] the Foley catheter. The lubricant-filled syringe of the SureStep tray is necessarily used before the water-filled syringe because a catheter must be lubricated before it is inserted and it must be inserted before it is inflated.
>
> Before the introduction of the SureStep tray, some practitioners inflated a test balloon using the water-syringe, and this step would have occurred before the catheter was lubricated. Thus, when a Foley catheterization procedure is performed which includes the step of inflating a test-balloon, the water-syringe may be used before the lubrication syringe. Such a procedure is not, however, performed using the SureStep tray. Bard specifically instructs its customers not to inflate a test balloon. . . .

Id. at 5–6. The interrogatory response also discussed a customer's deposition testimony to the effect that "not inflating a test balloon was a benefit of the SureStep tray as compared to previous trays" and stated that "Bard's instructions for use for the SureStep tray also expressly instruct users not to inflate a test balloon and those instructions are incorporated here by reference." [321-6] at 6.

Fact discovery closed on May 31, 2019. [187]. That same day (May 31, 2019, the close of fact discovery, Bard served supplemental interrogatory responses, including a "Second Supplemental Response to Interrogatory No. 4," in which Bard elaborated on its order of use claim construction theory. [312-23] at 6–7.

Medline served opening expert reports of Dr. John Abraham and Nurse Barbara Weintraub on August 1, 2019, and then served a corrected opening report of Barbara Weintraub on March 3, 2020. [312-2] ¶ 18. In the corrected expert report, Nurse Weintraub opined:

> To the extent that Bard has contended that that the water syringe is not "used" first because the water is not injected from the syringe until after the catheter has been lubricated, I disagree with Bard. Bard specifically contends, in its May 31, 2019 response to Interrogatory No. 4, "A water syringe is only used first during a Foley catheterization procedure when a test balloon is inflated, but Bard instructs its customers not to inflate a test balloon." Bard is incorrect.
>
> The water syringe is used when it is removed from the kit and attached to the catheter in preparation for inflation. This step occurs before the lubrication syringe is accessed. It is not necessary to inflate the balloon in order for the syringe to be "used." Nothing in the patent indicates that "use" is somehow limited to depressing the plunger on the syringe, and in fact the patent instead teaches that use is by accessing each syringe. "For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use."

[313-3] ¶¶ 354–55.

Expert discovery closed on July 28, 2020, almost five months after Nurse Weintraub's corrected opening report was served. [276]; [280]; [283].

Bard contends that its non-infringement contentions were vague and conclusory because Medline's infringement contentions were equally vague and conclusory. But Medline has provided specific record citations showing how its infringement contentions explained its infringement theory as to order of use, including annotated pictures of the SureStep Kit. [332-1] at 1–10 ¶¶ 1–9. Granted, although Medline seems to suggest that Bard's position on the order of use of the syringes was disclosed only in Bard's rebuttal expert reports of Dr. Hillstead and Dr. Yun, which were served on September 19, 2019, [312-2] ¶ 19, Medline demonstrated some awareness of this issue earlier. Medline submitted an interrogatory to Bard on the issue on April 10, 2019. However, far from indicating

knowledge that Bard would take that position, the interrogatory by definition sought to discover whether Bard would take that position. Nonetheless, Medline was at least aware enough of the order of use argument that it asked one of its experts (Nurse Weintraub) to opine on the matter in her opening expert report. But even then, the expert report reflects some uncertainty over Bard's position ("To the extent that Bard has contended . . .", [313-3] ¶ 354).

Ultimately, as noted above, "[t]he purpose of . . . the local patent rules in general, is to require parties to crystallize their theories of the case early in the litigation so as to prevent the shifting sands approach to claim construction." *Keranos,* 797 F.3d at 1035 (internal quotation marks omitted); *see also RTC Indus., Inc. v. Fasteners for Retail, Inc.*, No. 17 C 3595, 2020 WL 4815948, at *5 (N.D. Ill. Aug. 19, 2020). District courts are given "broad deference" to enforce local patent rules. *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005). Bard did not disclose its order of use theory in its final non-infringement contentions filed on September 29, 2017. The subsequent interrogatories and expert reports reflect a "shifting sands approach to claim construction." *Keranos*, 797 F.3d at 1035 (internal quotation marks omitted). Other courts in this district have strictly enforced the local patent rules and prohibited parties from relying on non-infringement theories not disclosed in final non-infringement contentions. *See* Order at 8, *Medline I*, No. 14-cv-3618, ECF No. 694; *see also Sloan Valve Co. v. Zurn Indus., Inc.*, No. 10-cv-00204, 2013 WL 6132598, at *11–12 (N.D. Ill. Nov. 20, 2013) (prohibiting defendant from raising non-infringement theory not disclosed in final non-infringement contentions at summary judgment). The court will do the same here.

Accordingly, Bard may not rely on a non-infringement theory that it did not disclose in its final non-infringement contentions in order to seek summary judgment of non-infringement of claims 1–8 and 10 of the '352 patent. On this ground alone, with respect to the '352 patent, Medline's motion for partial summary judgment of infringement [312] is granted and Bard's motion for summary judgment of non-infringement [315] is denied.

B. Claim Construction Of The Term "Use"

As an independent ground besides waiver, the parties dispute the meaning of the term "use" of a syringe. The court did not construe this term during the *Markman* process. "When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Intern. Ltd. v. Beyond Innovation, Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). Nothing prevents a court from construing claim terms at the summary judgment stage without a claim construction hearing. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (holding that claim construction may "be done in the context of dispositive motions such as those

seeking judgment as a matter of law"). Claim construction is a question of law decided by the court. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000).

Medline argues that the term "use" should be construed in the context of the claim, i.e., as "use during the catheterization procedure" rather than simply the word "use" standing alone; that read in the context of the specification and from the perspective of a person of ordinary skill in the art, "use during the catheterization procedure" means "accessed and manipulated by a clinician performing a catheterization procedure." Bard contends that the ordinary meaning and proper construction of "use" of a "syringe" as those terms appear in the patents means "injecting stored contents" (i.e., depressing the plunger).

The court agrees with Medline that "use" as that term is presented in claim 1 of the '352 patent—in the context of the complete claim language and the specification—means for a clinician to access and manipulate an item to perform a step in the catheterization procedure. Accordingly, a syringe is in "use" or "used" when it is employed in any way for a step in the Foley catheterization procedure.

"Judicial 'construction' of patent claims aims to state the boundaries of the patented subject matter, not to change that which was invented." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015). Claim terms are "generally given their ordinary and customary meaning": "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "The terms used in patent claims are not construed in the abstract, but in the context in which the term was presented and used by the patentee, as it would have been understood by a person of ordinary skill in the field of the invention on reading the patent documents." *Fenner Invs.*, 778 F.3d at 1322–23. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316.

As to intrinsic and extrinsic evidence: "The intrinsic record includes the claims, the specification, and the prosecution history." *Creative Integrated Sys., Inc. v. Nintendo of Am., Inc.*, 526 F. App'x 927, 932 (Fed. Cir. 2013); *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventory testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (internal quotation marks omitted). "[R]eliance on extrinsic evidence to interpret claims is proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997); *see also Phillips*,

415 F.3d at 1317, 1319 (extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language" (internal quotation marks omitted)). "[C]ourts engaging in claim construction generally follow the following hierarchy of evidence: (i) claim language, (ii) other intrinsic evidence, and (iii) extrinsic evidence." *CAO Lighting, Inc. v. Light Efficient Design*, No. 17-cv-7359, 2019 WL 1468139, at *2 (N.D. Ill. Apr. 3, 2019).

The court begins with the intrinsic evidence—"the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

Here, the claim term "use" has a readily apparent meaning in context. A person of skill in the art would understand the term "use," in the particular context of the '352 patent, to mean to access and manipulate an item to perform a step in the catheterization procedure.

First, "use" precedes "during the catheterization procedure" in the '352 patent. In the context of the claim's language, there is no ambiguity as to the definition of "use." A person of skill in the art would understand that a syringe is in "use" or "used" during the Foley catheterization procedure when it is being employed in any way for a step in the procedure.

This definition also accords with general purpose dictionary definitions of "use." The Oxford English Dictionary defines the noun "use" to mean: "The act of putting something to work, or employing or applying a thing, for any (esp. a beneficial or productive) purpose; the fact, state, or condition of being put to work, employed, or applied in this way; utilization or appropriation, esp. in order to achieve an end or pursue one's purpose." *Use*, Oxford English Dictionary, http://www.oed.com/view/Entry/220635?rskey=yJevu8&result=1&isAdvanced=false#eid (last visited January 30, 2023); *see also Use*, Webster's New World College Dictionary, (5th ed. 2014) (defining the verb "use" as "to put or bring into action or service; employ for or apply to a given purpose" and the noun "use" as "the act of using or the state of being used").

Bard contends that the plain and ordinary meaning of "use" of a syringe is injecting stored contents. Bard makes this argument by construing the term "syringe" and citing medical dictionaries' definitions of "syringe" to confirm that the meaning of "use" of a "syringe" is to inject or withdraw fluids. [315] at 8–9. To the extent Bard attempts to construe the term "syringe," the plain and ordinary

meaning of that term—in the context of this particular patent, claim, and specification—is readily apparent and requires no construction.

Even accepting Bard's dictionary definition of "syringe" as an object with the ultimate purpose "to inject or withdraw fluids," this does not change the definition of "use" in the context of the '352 patent. Bard's argument would have some appeal if the terms "syringe" and "use" were considered in the abstract, outside the context of the intrinsic evidence—the patent, the complete context of the claim, and the complete context of the specification. But that analysis would conflict with the principle that claim construction turns first on the intrinsic evidence.

Bard's reliance on specialized medical dictionaries to limit the plain meaning of the term "use" to injecting the contents of a syringe contradicts the plain and ordinary meaning of the term "use" in the context of the claim language (and in the context of the specification, as discussed below). *See Intel Corp. v. VIA Tech., Inc.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003) ("When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained."). As is apparent from the plain and ordinary meaning of the term "use" in the context of this claim and specification, a syringe is in "use" or "used" during the Foley catheterization procedure when it is employed in any way for a step in the Foley catheterization procedure. In other words, a syringe is in "use" or being "used" when it is attached to the catheter; it is also in "use" or being "used" when its fluid contents are injected into the tray (lubrication syringe) or the catheter (water syringe). A syringe is not in "use" only when its contents are being injected.

Bard's definition also relies on an erroneous understanding of the term "use" in the context of the entire claim. Bard's definition assumes that an object is only in "use" when it is being employed for its final purpose. But an object may be in "use" when it is being employed for a step in a process, even if that step is not the ultimate step in a process. Here, the water syringe during the Foley catheterization procedure must be (1) attached to the catheter and (2) depressed in order to inject its contents into the catheter balloon so that the catheter remains in place. Some practitioners may or may not perform an alternative initial step of testing the catheter balloon prior to catheter insertion. But the syringe is not in "use" or being "used" only when its contents are being injected.

The '352 patent's specification further supports defining "use" as to manipulate an item to perform a step in the procedure. *See Vitronics Corp.*, 90 F.3d at 1582 ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."). All figures in the '352 patent's specification show that the water syringe is always depicted to the left of the lubrication syringe. [321-1] at 13–16 ¶ 35. The specification describes this arrangement as a "left-to-right *usage*

configuration." *Id.* at 23 ¶ 41 (emphasis added). The specification also states that the intuition of which syringe should be used first is "further enforced when the higher step portion is disposed farther to the left and in a left-to-right *usage* configuration." *Id.* at 23 ¶ 42 (emphasis added). Thus, the specification makes clear that a syringe is in "use" when it is first taken out of the tray and employed to perform a step in the Foley catheterization procedure.

Figure 15 of the '352 patent's specification illustrates an example of printed instructions for performing the Foley catheterization procedure. *Id.* at 23–24 ¶ 44; [332-1] at 11 ¶ 19. At step 2c, the specification instructs a practitioner: "Test balloon with water-filled syringe and leave syringe attached to catheter." [321-1] at 23–24 ¶ 44; [332-1] at 11–12 ¶ 19. Step 2d instructs: "Inject lubricating jelly from syringe into wall of tray, then lubricate catheter tip." [321-1] at 23–24 ¶ 44; [332-1] at 11–12 ¶ 19. In these illustrative embodiments, the water syringe is "used" first because a practitioner picks up the syringe and attaches it to the catheter prior to picking up and injecting the lubrication syringe's contents into the tray. Even if a practitioner did not test the balloon first with water, the practitioner must still put the water syringe to "use" before the lubrication syringe by picking up the water syringe and attaching it to the catheter.

Bard argues that the '352 specification directs practitioners to test the balloon by inflating it with water from the water syringe (i.e., using the water syringe) before lubricating the catheter with the lubricating syringe (i.e., using the lubricating syringe). In contrast, Bard argues, the SureStep Kit's Directions for Use instruct practitioners *not* to test the balloon first (i.e., direct practitioners not to "use" the water syringe first). At Step 10, the directions instruct: "Attach the water filled syringe to the inflation port." [321-1] at 11 ¶ 25. Immediately below that instruction in all caps and bold is: "**NOTE: IT IS NOT NECESSARY TO PRE-TEST THE FOLEY CATHETER BALLOON**." *Id.* At Step 11, the directions instruct practitioners to "[r]emove Foley catheter from wrap and lubricate catheter" and, at Step 12, to prepare the patient for insertion. *Id.* (Then, at Step 14, the directions instruct practitioners to "[i]nflate catheter balloon using entire 10cc of sterile water provided in the prefilled syringe.") Bard also points to expert depositions to support its claim that the SureStep Kit does not require practitioners to use the water syringe to test the catheter balloon prior to inserting the catheter. Bard's experts explained that testing the catheter balloon by inflating it with the water syringe prior to insertion was common practice but is no longer common. [315-1] ¶ 45.[3] Thus, according to Bard, the SureStep Kit instructs practitioners to "use" the lubrication syringe first because it tells practitioners *not* to inject the water syringe first (not to inflate a test balloon).

[3] Medline has pointed to testimony from its own experts stating that some nurses still test the catheter balloon prior to insertion. [319-1] at 20–21 ¶ 46. For the reasons explained later in the text, the dispute about whether the catheter balloon is tested prior to insertion is not material and does not preclude summary judgment.

But the '352 patent's specification states that "[a]t [step 2], the health care services provider prepares the catheter . . . [which] *may include* filling a test balloon of the catheter assembly with water as shown at [step 2(c) of Figure 15]." [332-1] at 14 ¶ 27 (emphasis added). Thus, the specification does not mandate that practitioners inflate a test balloon first (i.e., use the water syringe first). Nor do the SureStep Kit directions categorically instruct practitioners not to test the balloon first; the directions note that "it is not necessary to pre-test" the balloon, but that falls short of an outright prohibition. Finally, a practitioner must attach the water syringe to the catheter in order to perform the Foley catheterization procedure, whether or not the practitioner test inflates the catheter balloon. A practitioner "uses" the water syringe when the practitioner removes the water syringe and attaches it to the catheter, regardless of whether the practitioner also then test inflates the catheter balloon. (Thus, any fact dispute over whether clinicians in practice continue to test the balloon is not material.)

Bard also argues that in *Medline III*, another court in this district construed the term "use" to mean injecting fluids. [315] at 10. But *Medline III* did not construe the claim term "use." The court concluded that the term "use" was "clear in the context," required no construction, and that it would be "redundant to say that it is for injecting fluids where a [person of skill in the art] reading the entire patent would understand that to be what 'use' means in context." *Medline Indus., Inc. v. C.R. Bard, Inc.*, No. 17-cv-7216, 2019 WL 337130, at *3 (N.D. Ill. Jan. 28, 2019). Both parties in this case have proposed different constructions of the term "use," and so construction is necessary. Moreover, *Medline III*'s understanding of the term "use" does not contradict the court's construction of the term adopted today; there is no dispute that a person of skill in the art would understand that "use" of a syringe includes injecting fluids. But a person of skill in the art would understand that a syringe is also in "use" or being "used" when it is employed for any step in the catheterization procedure—i.e., being removed from the tray and attached to the catheter.

In short, the plain and ordinary meaning of the term "use," in the context of the claim here ("use during the catheterization procedure"), in the context of the specification here, and from the perspective of a person of ordinary skill in the art, is for a clinician to access and manipulate an item to perform a step in the catheterization procedure. A syringe is in "use" or being "used" in the catheterization procedure when it is taken out of the tray and employed for a step in the procedure. The SureStep Kit meets the order of use limitation in claims 1-8 and 10 of the '352 patent.

C. Direct Infringement Of Claims 1–6, 8, and 10 of the '352 Patent

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "To prove infringement, the patentee must show that an accused product embodies all limitations of the claim either literally or by the doctrine of equivalents." *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1340 (Fed. Cir. 2013). Here, only literal infringement is relevant. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). The patentee bears the burden of proving infringement by a preponderance of the evidence. *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018). A court may enter a finding of infringement on summary judgment when no dispute of material fact exists and "when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Innovention Toys, LLC v. MGA Ent., Inc.*, 637 F.3d 1314, 1319 (Fed. Cir. 2011) (internal quotation marks omitted).

As the court has previously explained, the SureStep Kit meets the order of use limitation in claim 1 of the '352 patent (requiring syringes to be "ordered . . . in accordance with their use during the catheterization procedure"), and by extension in dependent claims 2–6, 8, and 10 of the '352 patent. No reasonable juror could conclude that the order of use limitation is not found in the accused SureStep Kit.

There is no genuine dispute of material fact that the SureStep Kit also meets every other limitation in claims 1–6, 8, and 10 of the '352 patent.

The other non-infringement theories Bard raised in its final non-infringement contentions as to claim 1 of the '352 patent were: (1) that the catheter of the SureStep Kit is not "attached" to a fluid bag; (2) that the limitation "lubricating jelly application compartment" was not present; and (3) that the limitations "the perimeter wall terminates at a horizontal flange" and (4) "the perimeter wall extends from at least a portion of the first compartment base member to the horizontal flange by a height that is greater than or equal to half of another height that the perimeter wall extends from the second compartment base member to the horizontal flange" were not present. [321-1] at 28, 33 ¶¶ 60, 65, 67, 68. Again, claims 2–6, 8, and 10 depend on claim 1, so all arguments regarding infringement or non-infringement as to claim 1 apply to these claims as well.

There is no genuine dispute of material fact that the SureStep Kit's catheter is "attached" to the fluid bag via tubing. [321-1] at 28 ¶ 61; [332-1] ¶ 30. "As the 'put up or shut up' moment in a lawsuit, summary judgment requires a non-moving

party to respond to the moving party's properly-supported motion by identifying specific, admissible evidence showing that there is a genuine dispute of material fact for trial." *Grant v. Trustees of Indiana Univ.*, 870 F.3d 562, 568 (7th Cir. 2017) (citation and internal quotation marks omitted). Bard takes the position that the term "attached" in claim 1 means "directly attached," while Medline contends that the term means "attached via tubing." But neither party moved for claim construction on this term. Medline argues that its experts established the presence of the "attached" claim limitation (and all other claim limitations), and properly cites the record (its experts' reports) in support. [321-1] at 28 ¶¶ 61–62. Medline further points out that the only claim limitation for which Bard's experts disclosed any non-infringement position for these claims was the "order of use" limitation. Bard's response does not cite any opinion from its experts' non-infringement rebuttal reports regarding the term "attached." Nor did Bard's own expert dispute that attachment via tubing constitutes attachment within the meaning of the claims. [321-1] at 28 ¶ 63. On this record, a reasonable juror could only conclude that the SureStep catheter is attached to the fluid bag. Accordingly, the claim limitation that the catheter be attached to the fluid bag in claim 1 of the '352 patent is met.

There is also no dispute of fact that the SureStep Kit meets the "lubricating jelly application compartment" limitation and the perimeter wall limitation in claim 1. Bard's response to Medline's motion for partial summary judgment raises no dispute of material fact that the SureStep Kit meets these limitations.

Turning to some additional arguments that relate to some but not all of claims 1–6, 8, and 10: Medline accuses only the SureStep Bag Kits (not the SureStep Meter Kits) of infringing claims 4 and 8 of the '352 patent. [321-1] at 34 ¶ 70. Thus, although Bard disputed that the SureStep Meter Kits meet additional limitations of claims 4 and 8, this dispute is immaterial. As to claims 3 and 10, Bard has cited no record evidence showing a genuine fact dispute as to claims 3 (that the SureStep Kit meets claim 3's limitation that the kit contain "printed instructions for using the single level tray") and 10 (that claim 10 does not require an opening in the wall between compartments). Accordingly, Bard has not raised a genuine issue of material fact for trial as to non-infringement of claims 1–6, 8, and 10 of the '352 patent.

Based on the undisputed facts and drawing all reasonable inferences in Bard's favor, a reasonable juror could only conclude that all limitations of claims 1–6, 8, and 10 of the '352 patent are present in the SureStep Kit. Summary judgment of infringement for claims 1–6, 8, and 10 of the '352 patent is granted in Medline's favor.

D. Partial Summary Judgment Under Rule 56(g)

Medline's motion for partial summary judgment argues that, if the court accepts Medline's definition of "use," then Medline is entitled to partial summary judgment pursuant to Federal Rule of Civil Procedure 56(g) that the limitation requiring the syringes to be "ordered . . . in accordance with their use during the catheterization procedure" in claims 1–8 and 10 of the '352 patent is met. [312-1] at 16–17.

Rule 56(g) provides that "[i]f the court does not grant all the relief requested by the motion, it may enter an order stating any material fact — including an item of damages or other relief — that is not genuinely in dispute and treating the fact as established in the case." Fed. R. Civ. P. 56(g).

Because the court grants partial summary judgment of infringement in Medline's favor with respect to claims 1–6, 8, and 10 of the '352 patent, the court has granted all the relief requested by the motion with respect to those claims. So there is no need to address the request for relief under Rule 56(g) with respect to limitations in those claims.

Medline also requests partial summary judgment under Rule 56(g) as to claim 7 of the '352 patent. Claim 7 depends on claim 1 and also includes the limitation "the contoured surface defining a mnemonic device indicating which of the first syringe or the second syringe should be *used first in the catheterization procedure*" (emphasis added)—i.e., this limitation incorporates the word "use[ ]." Given the court's construction of "use" explained above, Medline's request for partial summary judgment under Rule 56(g) is granted in that Bard is precluded from advancing its "use" argument as to claim 7.

II. Medline's Motion For Summary Judgment On Bard's Fifth Additional Defense of Patent Exhaustion, Implied License, and Equitable Estoppel [310]

Medline moves for summary judgment on Bard's Fifth Additional Defense of Patent Exhaustion, Implied License, and Equitable Estoppel. For the following reasons, the motion [310] is granted. Summary judgment is entered in Medline's favor on Bard's Fifth Additional Defense.

A. Patent Exhaustion

Medline explains that it has a distribution division that distributes not only Medline's own products but also Bard's SureStep Kit. [310-2] ¶¶ 7–8. Medline contends, however, that Medline's distribution of the SureStep Kit cannot support a defense of patent exhaustion because Bard directly infringes the '352 patent by

importing and offering the SureStep Kit for sale before any distribution by Medline. [310-1] at 8–9. That is, Medline argues that Bard's infringement occurs before Medline sells any SureStep Kit through Medline's distribution division. *Id.* Medline contends that patent exhaustion would only apply here if Bard were an authorized acquirer to which Medline had given prior authorization to manufacture products that infringe the '352 patent. Medline argues that Bard is not an authorized acquirer, so Bard directly infringes the patent without regard to any distribution done by Medline. *Id.*

The doctrine of patent exhaustion prohibits a patent owner from controlling the use or disposition of a product after ownership has passed to a purchaser. *Impression Prod., Inc. v. Lexmark Int'l., Inc.*, 137 S. Ct. 1523, 1531 (2017). "[T]he initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Computer, Inc. v. LG Elec., Inc.*, 553 U.S. 617, 625 (2008). "[P]atent exhaustion is uniform and automatic. Once a patentee decides to sell—whether on its own or through a licensee—that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license." *Impression Prod.*, 137 S. Ct. at 1535.

The doctrine of patent exhaustion generally applies downstream to "authorized acquirers" and "eliminates the legal restrictions on what authorized acquirers can do with an article embodying or containing an invention whose initial sale (or comparable transfer) the patentee authorized." *Helferich Patent Licensing, LLC v. N.Y. Times, Co.*, 778 F.3d 1293, 1301 (Fed. Cir. 2015). "The doctrine has never applied unless, at a minimum, the patentee's allegations of infringement, whether direct or indirect, entail infringement of the asserted claims by authorized acquirers—either because they are parties accused of infringement or because they are the ones allegedly committing the direct infringement required by the indirect infringement charged against other parties." *Id.* at 1302.

Bard's argument that patent exhaustion applies here because Medline's experts partly rely on the sale of Bard's products in their damages model is inapposite. [323] at 10. That argument concerns the accuracy and relevance of Medline's theory of damages, not whether patent exhaustion applies. Bard does not cite caselaw contradicting the well-established rule that patent exhaustion applies only where a patentee has sold its patent rights to an authorized user and is then prohibited from reasserting its patent rights.

As a matter of law, patent exhaustion does not apply here. Bard is not an authorized acquirer. Medline has accused Bard of infringement based on Bard's own manufacture, importation, and sale of the SureStep Kit regardless of Medline's own sale of the product. The fact that Medline sells the SureStep Kit through its distribution division is immaterial for the question of patent exhaustion.

B. Implied License

Medline also contends that its distribution of the SureStep Kit does not constitute an implied license for Bard to practice the '352 patent because Bard infringes the patents by manufacturing and importing the SureStep Kit regardless of any distribution by Medline. [310-1] at 10–11.

"A patent grants its owner the right to exclude others from making, using, or selling the patented invention." *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 878 (Fed. Cir. 1995). "However, all or part of the right to exclude may be waived by granting a license, which may be express or implied." *Id.* An implied license is a defense to patent infringement. *Id.* The existence of an implied license is a question of law. *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986).

Bard contends that Medline's Distributor Agreement with Bard's parent company, Becton, Dickinson and Company ("BD"), licensed Bard to sell the SureStep Kit to Medline. [323] at 11. Bard argues that implied license applies more broadly, not just in circumstances where the patentee has sold a product to a user to practice the patented invention. *Id.* at 12–13.

An implied license can be inferred from the totality of the parties' course of dealing and does not per se require an affirmative sale. *Wang Lab'y, Inc. v. Mitsubishi Elec. America, Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997). "In patent law, an implied license merely signifies a patentee's waiver of the statutory right to exclude others from making, using, or selling the patented invention." *Id.* "[I]mplied license looks for an affirmative grant of consent or permission to make, use, or sell: i.e., a license." *Id.* at 1581.

Even accepting Bard's broader definition of implied license, no reasonable juror could find an implied license based on the undisputed facts here. The 2006 Distributor Agreement between Medline and BD states that Medline "desires to distribute BD's products and provide sales and marketing services to BD." [329-1] ¶ 4. The Distributor Agreement does not specifically mention the SureStep Kit. Medline reaffirmed the Distributor Agreement with BD in 2018, after this litigation had commenced. *Id.* ¶ 5. The parties dispute some aspects of this reaffirmation, but there is no dispute that the reaffirmation does not specifically reference the SureStep Kit or contain any other language that could be construed as granting Bard an implied license to manufacture and import products that infringe Medline's patents. Rather, the Distributor Agreement appears to represent a general contract between Medline and Bard's parent BD in which Medline agrees to distribute a broad range of BD products. Even construing the facts in favor of Bard, they are insufficient to create a genuine issue that Medline granted Bard an implied license

to make or import products under the '352 patent by entering into a transaction with Bard's parent to distribute a variety of unspecified BD products.

The cases Bard cites further demonstrate why Bard's implied license defense fails as a matter of law. In *Wang Laboratories, Inc. v. Mitsubishi Electronics America, Inc.*, a patent holder coaxed Mitsubishi into the market to produce a single in-line memory module (SIMM) by providing Mitsubishi with designs, suggestions, and samples. 103 F.3d at 1582. The patentee purchased SIMMs from Mitsubishi and then years later accused Mitsubishi of infringement. *Id.* The Federal Circuit held that Mitsubishi properly inferred consent and had an implied license to the use of the invention. *Id.* The facts here are different. There are no facts indicating that Medline coaxed Bard into producing products that infringe Medline's patents, purchased accused products over a period of years from Bard directly, and then only years later accused Bard of infringement. While Medline admits that it purchased and distributed the SureStep Kit pursuant to the Distributor Agreement with BD, there is no indication that Medline did so intending to purchase and distribute the SureStep Kit specifically rather than as part of a larger Distributor Agreement involving many unspecified BD products.

Likewise, in *De Forest Radio Telephone & Telegraph Co. v. United States*, the patent holder of audions used in radio communication equipment sued the United States for infringement. 273 U.S. 236, 237 (1927). The Supreme Court concluded that the patentee had granted an implied license to the United States to use the audions because the patentee had not only given the United States "information, drawings, and blueprints" to aid in the manufacture of the audions but had also explicitly told the United States that it would not interfere in the immediate manufacture of the audions. *Id.* at 240–42. Based on the undisputed facts here, Medline has never assisted Bard in manufacturing the SureStep Kit, nor has it ever told Bard that it would not interfere in the manufacturing of the SureStep Kit.

Bard also contends that it would be inequitable if Medline could purchase infringing products, resell those products, and then receive damages for those sales. [323] at 12. Again, this is an argument related to damages. Whatever the significance of Medline's participation in selling the SureStep Kit through the Distributor Agreement with BD, it does not support the application of the doctrine of implied license.

Bard further argues that its importation of the SureStep Kit is licensed conduct because Bard is required to import the SureStep Kit into the United States in order to fulfill Medline's purchase orders. [323] at 13. Bard cites no record evidence that Bard must import the SureStep Kit specifically in order to fulfill BD orders under the Distributor Agreement. The facts do not support the conclusion (nor is there a genuine issue for trial) that Medline has given Bard a license to manufacture and import products that infringe the '352 patent. Medline has a

Distributor Agreement with Bard's parent, BD, in which Medline agreed to act as a distributor of a variety of BD products, not specifically the SureStep Kit. Summary judgment is granted for Medline on Bard's implied license defense.

C. Equitable Estoppel

Equitable estoppel requires a showing that: "(1) the patentee, through misleading conduct (or silence), leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relies on that conduct; and (3) the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim." *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013). "[T]he applicability of equitable estoppel is committed to the sound discretion of the trial judge." *Id.* (internal quotation marks omitted).

The undisputed facts here do not support the application of equitable estoppel, nor is there a triable issue as to equitable estoppel. Bard again relies on the Distributor Agreement and argues that Medline's actions misled Bard into thinking it should import the SureStep Kit. [323] at 14. But Bard cites no evidence supporting the conclusion that Bard was required to manufacture and import the SureStep Kit in order to fulfill orders under the Distributor Agreement. Medline filed the complaint in this case eight days after the '352 patent issued. [322] at 6 ¶¶ 26, 28. Bard also retained outside counsel as early as May 1, 2014, to review Medline's patents before Bard launched the SureStep Kit. *Id.* at 6 ¶ 25. It is not credible that Medline's conduct led Bard to reasonably infer that it could manufacture and import products that infringed the '352 patent when Bard had commissioned outside counsel to review Medline's patents as early as 2014, before Bard launched the SureStep Kit. For these same reasons, Bard also has not shown that it has been prejudiced by Medline's conduct. Again, Medline sued Bard soon after the relevant patent issued. Bard chose to continue manufacturing and importing the SureStep Kit while aware that the product might infringe Medline's patent and that Medline intended to assert its rights under that patent.

Accordingly, Medline's motion for summary judgment [310] is granted. Judgment is entered in favor of Medline on Bard's Fifth Affirmative Defense.

CONCLUSION

Medline's motion for partial summary judgment of infringement, [312], is granted in part and denied in part. The motion is granted in the following respects: (1) summary judgment is granted for Medline and against Bard with respect to infringement of claims 1–6, 8, and 10 of the '352 patent; (2) under Rule 56(g), summary judgment is granted for Medline and against Bard in that Bard is precluded from advancing its "use" argument as to claim 7 of the '352 patent.

Bard's motion for summary judgment of non-infringement, [315], is denied with respect to the '352 patent. Medline's motion for summary judgment on Bard's Fifth Additional Defense, [310], is granted. All motions are denied without prejudice to the extent they request relief with respect to the '753 patent. That is, the court denies, without prejudice to refiling at the conclusion of the reexamination proceedings, (1) any relief requested with respect to the '753 patent in the motions already listed ([310], [312], [315]), as well as (2) Bard's motion for summary judgment of non-infringement of the '753 patent under 35 U.S.C. § 271(a), [314].

Date: March 31, 2024 /s/ Martha M. Pacold